K123049

510(k) Summary

Owner/Submitter	Q Core Medical Ltd. 29 Yad Haruzim St. Netanya 4250529 ISRAEL
Contact Person	Rhona Shanker FDA Regulatory Consultant to Q Core Medical Ltd Ph: 301251-9570 Fax: 301-251-9571 Rhonashanker07@verizon.net
Date of Submission	24 September 2012
Trade Name	Sapphire Infusion Pump System with Administration Sets
Common Name	Infusion pump
Classification Name	Infusion Pump 21 CFR 880.5725 Product Codes: FRN - Infusion pump MEA - Patient controlled analgesia (PCA) infusion pump MRZ - Infusion pump accessories (administration sets)
Predicate Device Infusion Pump	AP34 Multi-therapy Infusion pump (K082182) Spectrum Infusion Pump with Master Drug Library (K042121), CADD-Prizm Model 6101 Ambulatory Infusion Pump (K000842) Bodyguard Infusion Pump System (K060479)
Administration Sets	Q Core Administration Sets cleared under K082182

OCT 17 2013

Device Description

The Q Core Sapphire infusion pump the result of modifications to the FDA cleared AP 34 Infusion pump (K082182). The modifications were changes to the user interface and additional functions that include new delivery modes and the Drug Library feature. There are no changes to the basic infusion pump technology. Like its predicates, the Sapphire is a single-channel, volumetric infusion pump that is intended for controlled delivery through intravascular,

subcutaneous, intra-arterial and epidural routes. It is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, epidural medication, blood and blood products and includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural. The pump has alarms for occlusions, air in the line, administration set installment issues, and internal battery issues. The Pump includes software and is powered by an external power source or by an internal battery. It is intended to be used by both licensed health care professionals in the clinical environment, and home users in an ambulatory environment. The Sapphire pump is designed to follow the patient through the various care areas, and in pre-hospital medical ground transportation.

The dedicated Q Core Administration Sets for the Sapphire infusion pump are provided sterile and are for single-patient use and single use only.

Indications for Use

The Q Core Sapphire infusion pump is intended for the controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition, lipids, IV medication, epidural medication, blood and blood products.

The Sapphire pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural.

The pump is intended to be used by both licensed health care professionals in a clinical environment, and home users in an ambulatory environment. The Sapphire pump is designed to follow the patient through the various care areas, and in pre-hospital medical ground transportation.

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

Technological Characteristics

The Sapphire infusion pump is similar to the predicate devices in the following respects:

1. All pumps are volumetric and software controlled.
2. All pumps are indicated for the controlled delivery of programmed doses of saline, TPN, lipids, IV medication, epidural medication at selected rates and can be used in the hospital, pre-hospital medical ground transporation, and home environments.
3. The Sapphire pump has six delivery modes: Continuous, Intermittent, Multi-step, PCA, TPN, and Epidural. Each of the predicates includes at least three of these modes.
4. The pump is substantially equivalent to the Spectrum Infusion Pump with Master Drug Library (K042121) with respect to the delivery of blood and blood products.
5. All pumps have similar safety features to prevent free flow, alarms for the detection of upstream and downstream occlusions, low battery, end of infusion, and pump failure, and authorization levels to prevent misuse.

The Q Core Administration Sets are similar to the predicate sets cleared under K082182 in the

following respects:

1. All sets are dedicated for use with Q Core infusion pumps.
2. All sets are indicated for intravenous infusion.
3. All sets can be used only by or under the order of a licensed medical practitioner.
4. All sets consist of standard, conventional components such as Luer locks, PVC tubing, Y-connector, tubing clamp.
5. All sets use materials with the same characteristics (biocompatible, non-DEHP, latex free).
6. All sets have the same means to protect against free flow (cassette with an Anti-Free Flow Valve [AFFV]).
7. All sets are provided sterile, non-pyrogenic, intended for single patient use and single use.
8. All sets are intended for either hospital or home use.

Pre-Clinical Testing

Preclinical testing included in the submission to demonstrate that the Sapphire Infusion Pump is safe and performs as intended involved the following:

Electrical Safety per IEC 60601-1
EMC testing per IEC 60601-1-2
Environmental Testing per 60601-1-11
Mechanical Testing per IEC 68-2
Alarm testing per IEC 60601-1-8
Software Verification and Validation per the FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* dated May 11, 2005
Pump accuracy per IEC 60601-2-24: Particular requirements for Safety of Infusion Pumps and Controllers
Human Factors testing

Testing of the Administration Sets involved:

Biocompatibility testing per ISO 10993
Testing per ISO 8536-4, Infusion Equipment for Medical Use, Part 4
Testing per ISO 1135-4, Transfusion Equipment for Medical Use
Sterilization Validation per ISO 11135-1
Sterile Packaging Validation
Shelf life

Conclusion

The Sapphire Infusion Pump is substantially equivalent to the AP34 Multi-therapy Infusion pump (K082182) (primary predicate) with respect to the indications for use, the target

population, and the locations of use. The Sapphire is also substantially equivalent to the Spectrum Infusion Pump with Master Drug Library (K042121), the CADD-Prizm Model 6101 Ambulatory Infusion Pump (K000842) and the Bodyguard Infusion Pump System (K060479) with respect to the basic indications for use (i.e., infusion pump that administers controlled doses of medications and parenteral nutritional feedings), additional delivery modes, additional products (blood and blood products), administration sites, target populations and locations of use.

The Sapphire Infusion Pump incorporates the same operating principle (linear peristaltic infusion pump) as the AP 34 Infusion Pump, the Spectrum Infusion Pump, and the CADD Prizm Model 6101 Infusion Pump. The Pump has delivery modes (Continuous, Intermittent, Multi-step, PCA, TPN and Epidural) that are also provided by the predicate devices, and has alarms for occlusions, air in the line, administration set installment issues, and internal battery issues. The Q Core Administration Sets that are to be used with the Sapphire pump are substantially equivalent to those cleared under K082182.

In summary, the Sapphire Infusion Pump and its dedicated Administration Sets are substantially equivalent to its predicates with respect to indications for use, target populations, types of infusions, delivery modes, technological characteristics and safety features.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

Q Core Medical LTD
C/O Rhona Shanker
Regulatory Consultant
12154 Darnestown Road, #236
GAITHERSBURG, MD 20878

Re: K123049
Trade/Device Name: Sapphire Infusion Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: October 15, 2013
Received: October 15, 2013

Dear Ms. Shanker

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123049

Device Name: Sapphire Infusion Pump System

Indications for Use:

The Q Core Sapphire infusion pump is intended for the controlled delivery through intravascular, subcutaneous, intra-arterial and epidural routes. The pump is designed to deliver saline, Total Parenteral Nutrition (TPN), lipids, IV medication, epidural medication, blood and blood products.

The Sapphire pump includes the following infusion modes for all intended uses: Continuous, Intermittent, TPN, PCA, Multi-step, and Epidural.

The pump is intended to be used by both licensed health care professionals in a clinical environment, and home users in an ambulatory environment and in pre-hospital medical ground transportation.

The dedicated Q Core administration sets for the Sapphire pump are intended for single-patient use and single-use only.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C. Chapman
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